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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,882	VAN BEUNINGEN, MARINUS GERARDUS JOHANNE	
	Examiner	Art Unit	
	Robert T. Crow	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. This action is in response to papers filed 19 May 2009 in which the specification and claims 1-8 were amended, no claims were canceled, and new claim 11 was added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections under 35 U.S.C. 112, second paragraph, are withdrawn in view of the amendments.

The previous rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are addressed following the rejections necessitated by the amendments.

The previous rejections under the judicially created doctrine of obviousness-type double patenting are withdrawn in view of Applicant's amendments. However, new rejections under the judicially created doctrine of obviousness-type double patenting are presented below.

Claims 1-9 and 11 are under prosecution.

2. This action is non-final in view of the new rejections under the judicially created doctrine of obviousness-type double patenting presented below.

Specification

3. The amendments to the specification filed 19 May 2009 are acknowledged and have been entered.

Claim Interpretation - 35 USC § 112, Sixth Paragraph

4. The following is a quotation of the sixth paragraph of 35 U.S.C. 112:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

5. As noted in the previous Office Action, Applicant has invoked 35 USC § 112 Sixth Paragraph in the limitation "means for transporting...sections" in lines 6-7 of claim 9. While the limitations meet the three-prong analysis for consideration under 35 USC § 112 Sixth Paragraph, the limitation "potential means" and the limitation "means for signal detection" are not being treated under 35 USC 112, sixth paragraph because the specification does not provide a limiting definition of the structural elements that define the structures of the means that provide the various functions found in the claims. Thus, the claims are given the broadest reasonable interpretation consistent with the specification (*In re Hyatt*, 211 F.3d1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000) (see MPEP 2111 [R-1]).

6. The following rejections are new rejections necessitated by the amendments.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-5, 7-8, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Ligler et al (U.S. Patent Application Publication No US 2002/0028475 A1, published 7 March 2002) as evidenced by the online dictionary at merriam-webster.com [retrieved on 2009-08-05; Retrieved from the Internet: <URL: www.merriam - webster.com/dictionary/tube>] and further as evidenced by Stanchfield et al (U.S. Patent No. 6,436,350 B1, issued 20 August 2002)

Regarding claim 1, Ligler et al teach a device comprising tubular housing in the form of column 14, which has a proximal end in to form of an open tip and a distal end in the form of the open top end of Figure 1 (paragraph 0032). Fluid flows through the column, which further comprises a flow-through support member in the form of porous membrane 12 (Figure 1 and paragraph 0032); the housing therefore defines an internal flow passageway. Porous membrane 12 is made of a metal oxide; namely, aluminum oxide (paragraph 0023), and obstructs the internal passageway of the housing (Figure 1). The membrane comprises through going channels (i.e., pores) suitable for allowing an interaction between target and probe molecules; namely, binding elements are immobilized throughout the thickness of the membrane (i.e., in the channels; paragraph

0024), wherein the binding elements are antibodies and are thus probes suitable for binding to a target analyte (paragraph 0025).

It is noted that a review of the specification yields no limiting definition of the shape of the "tubular" housing. The online dictionary at merriam-webster.com defines a tube as "usu." (i.e., usually) being cylindrical; thus, tubes are not necessarily cylindrical. In addition, Stanchfield et al define tubes as being either circular or "any other polygonal shape" (column 5, lines 45-50). Thus, because the housing of Ligler is either circular or a polygon (i.e., is round or has multiple sides), the housing is a tube and the claims are given the broadest reasonable interpretation consistent with the specification regarding a "tubular housing."

In addition, it is noted that the phrase "suitable for allowing" clearly indicates that the recitation of "an interaction between target and probe molecules" refers to an intended use of the claimed device, and does not actually require target or probe molecules. The courts have held that "while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In addition, "[A]pparatus claims cover what a device *is*, not what a device *does*." *Hewlett-Packard Co. v. Bausch &Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). Therefore, the various uses recited in claim 1 (e.g., allowing an interaction between target and probe molecules) fail to define additional structural elements of the

claimed device. Because Ligler et al teaches the structural elements of the claim, the claim is anticipated by Ligler et al. See MPEP § 2114.

Regarding claim 2, Ligler et al teach the device of claim 1, wherein the flow-through support member is provided with probe molecules suitable for interacting with target molecules; namely, binding elements are immobilized throughout the thickness of the membrane (i.e., in the channels; paragraph 0024), wherein the binding elements are antibodies and are thus probes suitable for binding to a target analyte (paragraph 0025).

Regarding claim 3, Ligler et al teach the device of claim 1, whereby the flow-through support member is provided near the distal end of the housing; namely, membrane 12 is near the distal (i.e., top) opening of the tube (Figure 1).

Regarding claim 4, Ligler et al teach the device of claim 1, wherein the flow-through support member is made of aluminum oxide (paragraph 0023).

Regarding claim 5, Ligler et al teach the device of claim 1, wherein the flow-through support member is optically transparent; namely, the flow-through support member is made of aluminum oxide (paragraph 0023). Page 8 of the instant specification states that metal oxides are highly transparent to visible light (i.e., optically transparent), and that aluminum oxide is a metal oxide. Thus, the claim has been given the broadest reasonable interpretation consistent with the specification regarding an "optically transparent" membrane.

Regarding claim 7, Ligler et al teach the device of claim 1, wherein the plane of the flow-through support member extends substantially perpendicular (i.e., normal) to the longitudinal axis of the housing (Figure 1 and paragraph 0027).

Regarding claim 8, Ligler et al teach the device of claim 1, wherein the flow-through support member spans the bore of the housing; namely, the membrane is positioned across the column (Figures 1-2 and paragraphs 0032-0033).

Regarding claim 11, Ligler et al teach the device of claim 1, wherein the through going channels have a pore size diameter between 50 and 400 nm; namely, the pore sizes are about 0.2 microns (paragraph 0022), which is about 200 nm. The channels also comprise probes; namely, binding elements are immobilized throughout the thickness of the membrane (i.e., in the channels; paragraph 0024), wherein the binding elements are antibodies and are thus probes suitable for binding to a target analyte (paragraph 0025).

Claim Rejections - 35 USC § 102(b)/103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-3, 5, and 7-8 are rejected under 35 U.S.C. 102(b) as anticipated by Raybuck et al (U.S. Patent No. 5,556,598, issued 17 September 1996) as evidenced by Beattie (U.S. Patent No. 6,426,183 B1, issued 30 July 2002) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Raybuck et al (U.S. Patent No. 5,556,598, issued 17 September 1996) in view of Beattie (U.S. Patent No. 6,426,183 B1, issued 30 July 2002).

Regarding claim 1, Raybuck et al teach a device comprising a tubular housing have a proximal end and a distal end defining an internal flow passageway; namely, Figure 6 shows a tubular housing in the form of pipette tip 10, which is shown having a proximal and distal end (i.e., the ends of the tip; column 8, line 58-column 9, line 55). The housing is further provided with a flow-through support member in the form of substrate 17 (column 7, lines 15-30), which obstructs the internal passage way of the housing (Figure 6). Substrate 17 is a membrane that is porous (column 5, lines 30-50), and thus comprises through going channels in accordance with the embodiment described in lines 24-35 on page 6 of the instant specification. Thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "channel."

The preceding rejection is based on judicial precedent following *In re Fitzgerald*, 205 USPQ 594, because Raybuck et al are silent with respect to silicon oxides. However, the recitation of membrane that is "a silicon oxide" in claim 1 is deemed to be inherent in the glass membrane of Raybuck et al, as evidenced by Beattie, which teaches that glass is SiO2, which is an oxide of silicon (column 2, lines 20-25). The

burden is on Applicant to show that the claimed membrane that is "a silicon oxide" is either different or non-obvious over the glass membrane of Raybuck et al.

Alternatively, Beattie teaches the attachment of biomolecules (i.e., probes) to glass, wherein the glass is an oxide of silicon (column 2, lines 10-30), which has the added advantage of allowing improved stable attachment of the probes to the surface without requiring derivatization (Abstract). Thus, Beattie teaches the known technique of using glass that is an oxide of silicon

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the device comprising the glass membrane as taught by Raybuck et al so that the glass membrane comprises an oxide of silicon as taught by Beattie to arrive at the instantly claimed device with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a device having a membrane having the added advantage of allowing improved stable attachment of the probes to the surface without requiring derivatization as explicitly taught by Beattie (Abstract). In addition, it would have been obvious to the ordinary artisan that the known technique of using glass that is an oxide of silicon as taught by Beattie could have been applied to the glass membrane in the device of Raybuck et al with predictable results because the known technique of using glass that is an oxide of silicon as taught by Beattie predictably results in use of a glass known to be reliable in binding assays.

As noted above, the phrase "suitable for allowing" clearly indicates that the recitation of "an interaction between target and probe molecules" refers to an intended use of the claimed device, and does not actually require target or probe molecules. As also noted above, apparatus claims cover what a device *is*, not what a device *does*." Therefore, the various uses recited in claim 1 (e.g., allowing an interaction between target and probe molecules) fail to define additional structural elements of the claimed device. Because Raybuck et al teach the structural elements of the claim, the claim is anticipated by Raybuck et al, or, alternatively, is obvious over Raybuck et al in view of Beattie.

Regarding claim 2, the device of claim 1 is discussed above. Raybuck et al teach the support member is provided with probe molecules suitable for interacting with target molecules; namely, capture entities are immobilized on the membrane (column 5, lines 50-60).

In addition, as noted above, apparatus claims cover what a device *is*, not what a device *does*. The phrase "suitable for interacting" clearly indicates an intended use of the claimed device. Therefore, the various uses recited in claim 2 (e.g., interacting with target molecules) fail to define additional structural elements of the claimed device. Because Raybuck et al teach the structural elements of the claim, the claim is anticipated by Raybuck et al.

Regarding claim 3, the device of claim 1 is discussed above. Raybuck et al also teach the support member is provided at or near the distal end of the housing (Figure 6).

Regarding claim 5, the device of claim 1 is discussed above. Raybuck et al further teach the support member is optically transparent (column 6, lines 10-20).

Regarding claim 7, the device of claim 1 is discussed above. Raybuck et al teach the plane of the support member extends substantially perpendicular with the longitudinal axis of the housing (Figure 6).

Regarding claim 8, the device of claim 1 is discussed above. Raybuck et al also teach the support member spans the bore of the housing; namely, the support member is placed entirely across the opening of tubular housing (Figures 2D-E); thus, the support member is at the end of the housing.

Claim Rejections - 35 USC § 103

11. Claims 1 and 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ligler et al (U.S. Patent Application Publication No US 2002/0028475 A1, published 7 March 2002) as evidenced by the online dictionary at merriam-webster.com [retrieved on 2009-08-05; Retrieved from the Internet: <URL: www.merriam-webster.com/dictionary/tube>] and further as evidenced by Stanchfield et al (U.S. Patent No. 6,436,350 B1, issued 20 August 2002) in view of van Damme et al (U.S. Patent No. 6,225,131 B1, issued 1 May 2001).

It is noted that this rejection applies to claim 1 to the extent that it is drawn to the embodiments of dependent claims 4-6.

It is also noted that while claims 4-5 have been rejected under 35 U.S.C 102(b) as described above in Section 8, the claims are also obvious using the alternative interpretation outlined below.

Regarding claims 4-6, Ligler et al teach the device of claim 1 comprising a tubular housing in the form of column 14, which has a proximal end in to form of an open tip and a distal end in the form of the open top end of Figure 1 (paragraph 0032). Fluid flows through the column, which further comprises a flow-through support member in the form of porous membrane 12 (Figure 1 and paragraph 0032); the housing therefore defines an internal flow passageway. Porous membrane 12 is made of a metal oxide; namely, aluminum oxide (paragraph 0023), and obstructs the internal passageway of the housing (Figure 1). The membrane comprises through going channels (i.e., pores) suitable for allowing an interaction between target and probe molecules; namely, binding elements are immobilized throughout the thickness of the membrane (i.e., in the channels; paragraph 0024), wherein the binding elements are antibodies and are thus probes suitable for binding to a target analyte (paragraph 0025).

As noted above, a review of the specification yields no limiting definition of the shape of the "tubular" housing. The online dictionary at merriam-webster.com defines a tube as "usu." (i.e., usually) being cylindrical; thus, tubes are not necessarily cylindrical. In addition, Stanchfield et al define tubes as being either circular or "any other polygonal shape" (column 5, lines 45-50). Thus, because the housing of Ligler is either circular or a polygon (i.e., is round or has multiple sides), the housing is a tube and the claims are

given the broadest reasonable interpretation consistent with the specification regarding a "tubular housing."

As also noted above, the phrase "suitable for allowing" clearly indicates that the recitation of "an interaction between target and probe molecules" refers to an intended use of the claimed device, and does not actually require target or probe molecules. The courts have held that apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in claim 1 (e.g., allowing an interaction between target and probe molecules) fail to define additional structural elements of the claimed device. Because the prior art teaches the structural elements of the claim, the claim is obvious over the prior art.

Ligler et al do not explicitly teach the channels of the aluminum oxide membrane are substantially coaxial with the longitudinal axis of the housing (i.e., claim 6).

However, van Damme et al teach flow-through support members in the form of transparent aluminum oxide membranes (i.e., claims 4-5) that are transparent (column 2, lines 5-15). The channels of the membrane are through going oriented channels that allow flow-through the membranes (column 3, lines 25-45), and are oriented perpendicular to the surface of sample application (claim 1 of van Damme). Van Damme et al also teach the membranes have the added advantage of allowing for assays using various optical techniques that also have advantageous surface chemical properties (column 2, lines 1-20). Thus, van Damme et al teach the known technique of using a flow-through support member that is a metal oxide (i.e., claim 4), transparent (i.e., claim 5), and has channels perpendicular to the flow direction (i.e., claim 6).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the device of Ligler et al so that the aluminum oxide membrane is the transparent aluminum oxide flow-through membrane (i.e., claims 4-5) having the channels perpendicularly oriented to the direction of flow as taught van Damme et al. Orientation of the membrane to allow flow-through that is perpendicular to the channels results in placement of the membrane so that the channels extend substantially coaxial with the longitudinal axis of the housing (i.e., claim 6), thus arriving at the instantly claimed device with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a device having the added advantage of allowing for assays using various optical techniques that also have advantageous surface chemical properties as explicitly taught by van Damme et al (column 2, lines 1-20). In addition, it would have been obvious to the ordinary artisan that the known technique of using the transparent metal oxide flow-through support member having the channel orientation as taught by van Damme et al could have been used as the aluminum oxide flow-through support member in the device of Ligler et al with predictable results because the known technique of using the transparent metal oxide flow-through support member having the channel orientation as taught by van Damme et al predictably results in use of a reliable flow-through support member.

12. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fields (U.S. Patent Application Publication No. US 2003/0027203 A1, published 9 February 2003) in view of Ligler et al (U.S. Patent Application Publication No US 2002/0028475 A1, published 7 March 2002).

Regarding claim 9, Fields teaches an apparatus having a handling station comprising a handling device; namely, an automated apparatus comprising a handling station comprising a handling device in the form of a robotic pipettor that transports pipette tips (paragraph 0065). The pipettor aspirates and dispenses fluids in the tip (paragraph 0065), and is thus a handling station comprising a handling device in accordance with the embodiment described on page 14 of the instant specification. The apparatus further comprises a robotic translation system for moving the handling station (i.e., pipette tips) in the form of a robotic arm (Figure 7 and paragraph 0065), which is a "means for transporting" in accordance with the embodiment of a means for transporting described on page 18 of the instant specification. The apparatus of Fields also comprises an incubation section in the form of a region of the device that comprises a heating block, which is a, incubation device for incubating the sample because the specification contains no limiting definition of an incubation section comprising an incubation device. Fields further teaches the apparatus comprises an analysis section comprising a detection assembly in the form of a fluorescence detector (claim 20 of), which is in accordance with the embodiment of a "detection means" presented on pages 16-17 of the instant specification. Thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a

"handling station" a "handling device" a "means for transporting," and "incubation section comprising an incubation device," and "an analysis section comprising a detection device."

Fields also teaches the use of a tip wherein nucleic acids bind to a porous material within a tip (Figures 8-9 and paragraphs 0067-0068). The tip is a tubular housing having a proximal end and a distal end defining an internal flow passageway (Figures 8-9). The housing comprises flow-through support material 73 provided therein to obstruct the internal passageway. The support member is a porous material capable of binding nucleic acids (paragraph 0067), and thus comprises through going channels in accordance with the embodiment described in lines 24-35 on page 6 of the instant specification. Thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "channel."

In addition, as noted above, it is noted that the phrase "suitable for allowing" clearly indicates that the recitation of "an interaction between target and probe molecules" refers to an intended use of the claimed device, and does not actually require target or probe molecules. As also noted above, apparatus claims cover what a device *is*, not what a device *does*." Therefore, the various uses recited in claim 1 (e.g., allowing an interaction between target and probe molecules) fail to define additional structural elements of the claimed device. Because the prior art teaches the structural elements of the claim, the claim is obvious over the prior art.

Fields does not explicitly teach the housing comprises a support material comprising a membrane of a metal oxide.

However, Ligler et al teach a device comprising a housing in the form of column 14, which has a proximal end in to form of an open tip and a distal end in the form of the open top end of Figure 1 (paragraph 0032) and which further comprises a flow-through support member in the form of porous membrane 12 (Figure 1 and paragraph 0032); the housing therefore defines an internal flow passageway. Porous membrane 12 is made of a metal oxide; namely, aluminum oxide (paragraph 0023), and obstructs the internal passageway of the housing (Figure 1). The membrane comprises through going channels (i.e., pores) suitable for allowing an interaction between target and probe molecules; namely, binding elements are immobilized throughout the thickness of the membrane (i.e., in the channels; paragraph 0024), wherein the binding elements are antibodies and are thus probes suitable for binding to a target analyte (paragraph 0025). Ligler et al also teach the aluminum oxide membrane has the added advantage of providing a fast flow-through rate and allowing reuse (paragraph 0021). Thus, Ligler et al teach the known technique of providing a membrane of a metal oxide in a housing.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the apparatus comprising a tubular housing having a porous flow-through support material as taught by Fields so that the support material is the aluminum oxide membrane of Ligler et al to arrive at the instantly claimed apparatus with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in an apparatus having the added advantage of having an aluminum oxide membrane that provides a fast flow-through rate and allows reuse as

explicitly taught by Ligler et al (paragraph 0021). In addition, it would have been obvious to the ordinary artisan that the known technique of using the aluminum oxide membrane of Ligler et al could have been used as the porous flow-through support material in the apparatus of Fields with predictable results because the known technique of using the aluminum oxide membrane of Ligler et al predictably results in use of a reliable membrane for binding assays.

13. Claims 1 and 4-6 are rejected under 35 U.S.C. 103(a) as obvious over Raybuck et al (U.S. Patent No. 5,556,598, issued 17 September 1996) in view of van Damme et al (U.S. Patent No. 6,225,131 B1, issued 1 May 2001).

It is noted that while claims 1 and 5 have been rejected under 35 U.S.C 102(b), alternatively under 35 U.S.C. 103(a) as described above in Section 10, the claims are also obvious using the alternative interpretation outlined below.

Regarding claims 1 and 4-6, Raybuck et al teach a device comprising a tubular housing have a proximal end and a distal end defining an internal flow passageway; namely, Figure 6 shows a tubular housing in the form of pipette tip 10, which is shown having a proximal and distal end (i.e., the ends of the tip; column 8, line 58-column 9, line 55). The housing is further provided with a flow-through support member in the form of substrate 17 (column 7, lines 15-30), which obstructs the internal passage way of the housing (Figure 6). Substrate 17 is a membrane that is porous (column 5, lines 30-50), and thus comprises through going channels in accordance with the embodiment described in lines 24-35 on page 6 of the instant specification. Thus, the claim has

been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "channel."

As noted above, the phrase "suitable for allowing" clearly indicates that the recitation of "an interaction between target and probe molecules" refers to an intended use of the claimed device, and does not actually require target or probe molecules. As also noted above, apparatus claims cover what a device *is*, not what a device *does*." Therefore, the various uses recited in claim 1 (e.g., allowing an interaction between target and probe molecules) fail to define additional structural elements of the claimed device. Because the prior art teaches the structural elements of the claims, the claims are obvious over the prior art.

Raybuck et al do not explicitly teach an aluminum oxide membrane (i.e., claims 1 and 4), a transparent membrane (i.e., claim 5) or that the channels are substantially coaxial with the longitudinal axis of the housing (i.e., claim 6).

However, van Damme et al teach flow-through support members in the form of transparent aluminum oxide membranes (i.e., claims 1 and 4-5) that are transparent (column 2, lines 5-15). The channels of the membrane are through going oriented channels that allow flow-through the membranes (column 3, lines 25-45), and are oriented perpendicular to the surface of sample application (claim 1 of van Damme). Van Damme et al also teach the membranes have the added advantage of allowing for assays using various optical techniques that also have advantageous surface chemical properties (column 2, lines 1-20). Thus, van Damme et al teach the known technique of

using a flow-through support member that is a metal oxide (i.e., claim 4), transparent (i.e., claim 5), and has channels perpendicular to the flow direction (i.e., claim 6).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the device of Raybuck et al so that the aluminum oxide membrane is the transparent aluminum oxide flow-through membrane (i.e., claims 1 and 4-5) having the channels perpendicularly oriented to the direction of flow as taught van Damme et al. Orientation of the membrane to allow flow-through that is perpendicular to the channels results in placement of the membrane so that the channels extend substantially coaxial with the longitudinal axis of the housing (i.e., claim 6), thus arriving at the instantly claimed device with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a device having the added advantage of allowing for assays using various optical techniques that also have advantageous surface chemical properties as explicitly taught by van Damme et al (column 2, lines 1-20). In addition, it would have been obvious to the ordinary artisan that the known technique of using the transparent metal oxide flow-through support member having the channel orientation as taught by van Damme et al could have been used as the aluminum oxide flow-through support member in the device of Raybuck et al with predictable results because the known technique of using the transparent metal oxide flow-through support member having the channel orientation as taught by van Damme et al predictably results in use of a reliable flow-through support member.

14. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fields (U.S. Patent Application Publication No. US 2003/0027203 A1, published 9 February 2003) in view of Raybuck et al (U.S. Patent No. 5,556,598, issued 17 September 1996) as evidenced by, or alternatively in view of, Beattie (U.S. Patent No. 6,426,183 B1, issued 30 July 2002).

Regarding claim 9, Fields teaches an apparatus having a handling station comprising a handling device; namely, an automated apparatus comprising a handling station comprising a handling device in the form of a robotic pipettor that transports pipette tips (paragraph 0065). The pipettor aspirates and dispenses fluids in the tip (paragraph 0065), and is thus a handling station comprising a handling device in accordance with the embodiment described on page 14 of the instant specification. The apparatus further comprises a robotic translation system for moving the handling station (i.e., pipette tips) in the form of a robotic arm (Figure 7 and paragraph 0065), which is a "means for transporting" in accordance with the embodiment of a means for transporting described on page 18 of the instant specification. The apparatus of Fields also comprises an incubation section in the form of a region of the device that comprises a heating block, which is a, incubation device for incubating the sample because the specification contains no limiting definition of an incubation section comprising an incubation device. Fields further teaches the apparatus comprises an analysis section comprising a detection assembly in the form of a fluorescence detector (claim 20 of), which is in accordance with the embodiment of a "detection means" presented on pages 16-17 of the instant specification. Thus, the claim has been given the broadest

reasonable interpretation consistent with the teachings of the specification regarding a "handling station" a "handling device" a "means for transporting," and "incubation section comprising an incubation device," and "an analysis section comprising a detection device."

Fields also teaches the use of a tip wherein nucleic acids bind to a porous material within a tip (Figures 8-9 and paragraphs 0067-0068). The tip is a tubular housing having a proximal end and a distal end defining an internal flow passageway (Figures 8-9). The housing comprises flow-through support material 73 provided therein to obstruct the internal passageway. The support member is a porous material capable of binding nucleic acids (paragraph 0067), and thus comprises through going channels in accordance with the embodiment described in lines 24-35 on page 6 of the instant specification. Thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "channel."

In addition, as noted above, it is noted that the phrase "suitable for allowing" clearly indicates that the recitation of "an interaction between target and probe molecules" refers to an intended use of the claimed device, and does not actually require target or probe molecules. As also noted above, apparatus claims cover what a device *is*, not what a device *does*." Therefore, the various uses recited in claim 1 (e.g., allowing an interaction between target and probe molecules) fail to define additional structural elements of the claimed device. Because the prior art teaches the structural elements of the claim, the claim is obvious over the prior art.

Fields does not explicitly teach the housing comprises a support material comprising a membrane of a metal oxide.

Raybuck et al teach a device comprising a tubular housing have a proximal end and a distal end defining an internal flow passageway; namely, Figure 6 shows a tubular housing in the form of pipette tip 10, which is shown having a proximal and distal end (i.e., the ends of the tip; column 8, line 58-column 9, line 55). The housing is further provided with a flow-through support member in the form of substrate 17 (column 7, lines 15-30), which obstructs the internal passage way of the housing (Figure 6). Substrate 17 is a membrane that is porous (column 5, lines 30-50), and thus comprises through going channels in accordance with the embodiment described in lines 24-35 on page 6 of the instant specification. Thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "channel." Raybuck et al also teach the membrane has the added advantage of being able to incorporate a large number of different types of specific binding partners (i.e., probes; column 5, lines 52-62).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the device comprising the support material as taught by Fields so that the membrane is the glass membrane of Raybuck et al to arrive at the instantly claimed device with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a device having a membrane having the added advantage of being able to incorporate a large number of different types of

probes as explicitly taught by Raybuck et al (column 5, lines 52-62). In addition, it would have been obvious to the ordinary artisan that the known technique of using glass membrane of Raybuck et al could have been applied as the support member in the device of Fields with predictable results because the known technique of using glass membrane of Raybuck et al predictably results in use of a support member known to be reliable in binding assays.

The preceding rejection is based on judicial precedent following *In re Fitzgerald*, because Raybuck et al are silent with respect to silicon oxides. However, the recitation of membrane that is "a silicon oxide" in claim 1 is deemed to be inherent in the glass membrane of Raybuck et al, as evidenced by Beattie, which teaches that glass is SiO2, which is an oxide of silicon (column 2, lines 20-25). The burden is on Applicant to show that the claimed membrane that is "a silicon oxide" is either different or non-obvious over the glass membrane of Raybuck et al.

Alternatively, Beattie teaches the attachment of biomolecules (i.e., probes) to glass, wherein the glass is an oxide of silicon (column 2, lines 10-30), which has the added advantage of allowing improved stable attachment of the probes to the surface without requiring derivatization (Abstract). Thus, Beattie teaches the known technique of using glass that is an oxide of silicon

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the device comprising the glass membrane as taught by Fields in view of Raybuck et al so that the glass membrane comprises an oxide of silicon as taught by Beattie to arrive at the instantly claimed

device with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a device having a membrane having the added advantage of allowing improved stable attachment of the probes to the surface without requiring derivatization as explicitly taught by Beattie (Abstract). In addition, it would have been obvious to the ordinary artisan that the known technique of using glass that is an oxide of silicon as taught by Beattie could have been applied to the glass membrane in the device of Fields in view of Raybuck et al with predictable results because the known technique of using glass that is an oxide of silicon as taught by Beattie predictably results in use of a glass known to be reliable in binding assays.

15. Claims 1 and 11 are rejected under 35 U.S.C. 103(a) as obvious over Raybuck et al (U.S. Patent No. 5,556,598, issued 17 September 1996) in view of Ligler et al (U.S. Patent Application Publication No US 2002/0028475 A1, published 7 March 2002) as evidenced by the online dictionary at merriam-webster.com [retrieved on 2009-08-05; Retrieved from the Internet: <URL: www.merriam-webster.com/dictionary/tube>] and further as evidenced by Stanchfield et al (U.S. Patent No. 6,436,350 B1, issued 20 August 2002)

It is noted that this rejection applies to claim 1 to the extent that it is drawn to the embodiment of dependent claim 11.

Regarding claim 11, Raybuck et al teach the device of claim 1 comprising a tubular housing have a proximal end and a distal end defining an internal flow

passageway; namely, Figure 6 shows a tubular housing in the form of pipette tip 10, which is shown having a proximal and distal end (i.e., the ends of the tip; column 8, line 58-column 9, line 55). The housing is further provided with a flow-through support member in the form of substrate 17 (column 7, lines 15-30), which obstructs the internal passage way of the housing (Figure 6). Substrate 17 is a membrane that is porous (column 5, lines 30-50), and thus comprises through going channels in accordance with the embodiment described in lines 24-35 on page 6 of the instant specification. Thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "channel."

Raybuck et al does not explicitly teach the housing comprises a support material comprising a membrane of a metal oxide having the claimed pore size.

However, Ligler et al teach a device comprising a housing in the form of column 14, which has a proximal end in to form of an open tip and a distal end in the form of the open top end of Figure 1 (paragraph 0032) and which further comprises a flow-through support member in the form of porous membrane 12 (Figure 1 and paragraph 0032); the housing therefore defines an internal flow passageway. Porous membrane 12 is made of a metal oxide; namely, aluminum oxide (paragraph 0023), and obstructs the internal passageway of the housing (Figure 1). The membrane comprises through going channels (i.e., pores) suitable for allowing an interaction between target and probe molecules; namely, binding elements are immobilized throughout the thickness of the membrane (i.e., in the channels; paragraph 0024), wherein the binding elements are antibodies and are thus probes suitable for binding to a target analyte (paragraph

0025). The through going channels have a pore size diameter between 50 and 400 nm; namely, the pore sizes are about 0.2 microns (paragraph 0022), which is about 200 nm. The channels also comprise probes; namely, binding elements are immobilized throughout the thickness of the membrane (i.e., in the channels; paragraph 0024), wherein the binding elements are antibodies and are thus probes suitable for binding to a target analyte (paragraph 0025). Ligler et al also teach the aluminum oxide membrane has the added advantage of providing a fast flow-through rate and allowing reuse (paragraph 0021). Thus, Ligler et al teach the known technique of providing a membrane of a metal oxide in a housing.

It is noted that a review of the specification yields no limiting definition of the shape of the "tubular" housing. The online dictionary at merriam-webster.com defines a tube as "usu." (i.e., usually) being cylindrical; thus, tubes are not necessarily cylindrical. In addition, Stanchfield et al define tubes as being either circular or "any other polygonal shape" (column 5, lines 45-50). Thus, because the housing of Ligler is either circular or a polygon (i.e., is round or has multiple sides), the housing is a tube and the claims are given the broadest reasonable interpretation consistent with the specification regarding a "tubular housing."

As also noted above, the phrase "suitable for allowing" clearly indicates that the recitation of "an interaction between target and probe molecules" refers to an intended use of the claimed device, and does not actually require target or probe molecules. As also noted above, apparatus claims cover what a device *is*, not what a device *does*." Therefore, the various uses recited in claim 1 (e.g., allowing an interaction between

target and probe molecules) fail to define additional structural elements of the claimed device. Because the prior art teaches the structural elements of the claims, the claims are obvious over the prior art.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the apparatus comprising a tubular housing having a porous flow-through support material as taught by Raybuck et al so that the support material is the aluminum oxide membrane having the pore sizes of Ligler et al to arrive at the instantly claimed apparatus with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in an apparatus having the added advantage of having an aluminum oxide membrane that provides a fast flow-through rate and allows reuse as explicitly taught by Ligler et al (paragraph 0021). In addition, it would have been obvious to the ordinary artisan that the known technique of using the aluminum oxide membrane of Ligler et al could have been used as the porous flow-through support material in the device of Raybuck et al with predictable results because the known technique of using the aluminum oxide membrane of Ligler et al predictably results in use of a reliable membrane for binding assays.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1-5, 7-8 and 11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 47-49 and 51-53 of copending Application No. 11/662,397 in view of Ligler et al (U.S. Patent Application Publication No US 2002/0028475 A1, published 7 March 2002) as evidenced by the online dictionary at merriam-webster.com [retrieved on 2009-08-05; Retrieved from the Internet: <URL: www.merriam -webster.com/dictionary/tube>] and further as evidenced by Stanchfield et al (U.S. Patent No. 6,436,350 B1, issued 20 August 2002).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 47-49 and 51-53 of the '397 Application describe all of

the limitations of the claims in the instant application; e.g., device comprising a flow-through support member (i.e., a solid porous support) comprising a metal (i.e., conductive material) and having channels therethorugh, and aluminum oxide. For example, instant claim 4 is drawn to a device having a flow-through support member (i.e., a solid porous support) comprising a metal (i.e., conductive material) and having channels therethorugh, wherein the support member is aluminum oxide. These limitations are met by claims 51 and 47-49 of the '397 claims. The additional limitations of the '397 claims are encompassed by the open claim language "comprising" found in the instant claims.

The '397 claims do not require the support member of the device be in a tubular housing.

However, Ligler et al teach a device comprising tubular housing in the form of column 14, which has a proximal end in to form of an open tip and a distal end in the form of the open top end of Figure 1 (paragraph 0032). Fluid flows through the column, which further comprises a flow-through support member in the form of porous membrane 12 (Figure 1 and paragraph 0032); the housing therefore defines an internal flow passageway. Porous membrane 12 is made of a metal oxide; namely, aluminum oxide (paragraph 0023), and obstructs the internal passageway of the housing (Figure 1). The membrane comprises through going channels (i.e., pores) suitable for allowing an interaction between target and probe molecules; namely, binding elements are immobilized throughout the thickness of the membrane (i.e., in the channels; paragraph

0024), wherein the binding elements are antibodies and are thus probes suitable for binding to a target analyte (paragraph 0025).

Ligler et al also teach binding elements are immobilized throughout the thickness of the membrane (i.e., in the channels; paragraph 0024), wherein the binding elements are antibodies and are thus probes suitable for binding to a target analyte (i.e., claim 2; paragraph 0025); membrane 12 is near the distal (i.e., top) opening of the tube (i.e., claim 3; Figure 1); the flow-through support member is made of aluminum oxide (i.e.., claim 4; paragraph 0023), which is transparent in accordance with page 8 of the instant specification (i.e., claim 5); the plane of the flow-through support member extends substantially perpendicular (i.e., normal) to the longitudinal axis of the housing (i.e., claim 7; Figure 1 and paragraph 0027); the membrane is positioned across the column (i.e., claim 8; Figures 1-2 and paragraphs 0032-0033); and that the pore sizes are about 0.2 microns (paragraph 0022), which is about 200 nm, and also comprise probes in the form of binding elements are immobilized throughout the thickness of the membrane (i.e., in the channels; paragraph 0024), wherein the binding elements are antibodies and are thus probes suitable for binding to a target analyte (i.e., claim 11; paragraph 0025).

It is noted that a review of the specification yields no limiting definition of the shape of the "tubular" housing. The online dictionary at merriam-webster.com defines a tube as "usu." (i.e., usually) being cylindrical; thus, tubes are not necessarily cylindrical. In addition, Stanchfield et al define tubes as being either circular or "any other polygonal shape" (column 5, lines 45-50). Thus, because the housing of Ligler is either circular or a polygon (i.e., is round or has multiple sides), the housing is a tube and the claims are

given the broadest reasonable interpretation consistent with the specification regarding a "tubular housing."

In addition, it is noted that the phrase "suitable for allowing" clearly indicates that the recitation of "an interaction between target and probe molecules" refers to an intended use of the claimed device, and does not actually require target or probe molecules. The courts have held that apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in claim 1 (e.g., allowing an interaction between target and probe molecules) fail to define additional structural elements of the claimed device. Because the prior teaches the structural elements of the claim, the claim is obvious over the prior art.

Ligler et al also teach the housing has the added advantage of allowing bioassays to be performed in a short period of time using minute quantities of analyte (paragraph 0009).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the apparatus of the '397 claims to comprise the tubular housing of Ligler et al to arrive at the instantly claimed apparatus with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in an apparatus having the added advantage of allowing bioassays to be performed in a short period of time using minute quantities of analyte as explicitly taught by Ligler et al (paragraph 0009).

This is a provisional obviousness-type double patenting rejection.

18. Claims 4-6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 47-49 and 51-53 of copending Application No. 11/662,397 in view of Ligler et al (U.S. Patent Application Publication No US 2002/0028475 A1, published 7 March 2002) as evidenced by the online dictionary at merriam-webster.com [retrieved on 2009-08-05; Retrieved from the Internet: <URL: www.merriam -webster.com/dictionary/tube>] and further as evidenced by Stanchfield et al (U.S. Patent No. 6,436,350 B1, issued 20 August 2002) as applied to claim 1 above, and further in view of van Damme et al (U.S. Patent No. 6,225,131 B1, issued 1 May 2001).

It is noted that while claims 4-5 have been rejected as described above in Section 17, the claims are also obvious using the alternative interpretation outlined below.

Regarding claims 4-6, the device of claim 1 is discussed above in Section 17.

Neither the '397 claims nor Ligler et al do not explicitly teach the channels of the aluminum oxide membrane are substantially coaxial with the longitudinal axis of the housing (i.e., claim 6).

However, van Damme et al teach flow-through support members in the form of transparent aluminum oxide membranes (i.e., claims 4-5) that are transparent (column 2, lines 5-15). The channels of the membrane are through going oriented channels that allow flow-through the membranes (column 3, lines 25-45), and are oriented perpendicular to the surface of sample application (claim 1 of van Damme). Van Damme et al also teach the membranes have the added advantage of allowing for

assays using various optical techniques that also have advantageous surface chemical properties (column 2, lines 1-20). Thus, van Damme et al teach the known technique of using a flow-through support member that is a metal oxide (i.e., claim 4), transparent (i.e., claim 5), and has channels perpendicular to the flow direction (i.e., claim 6).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the device of the '397 claims in view of Ligler et al so that the aluminum oxide membrane is the transparent aluminum oxide flow-through membrane (i.e., claims 4-5) having the channels perpendicularly oriented to the direction of flow as taught van Damme et al. Orientation of the membrane to allow flow-through that is perpendicular to the channels results in placement of the membrane so that the channels extend substantially coaxial with the longitudinal axis of the housing (i.e., claim 6), thus arriving at the instantly claimed device with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a device having the added advantage of allowing for assays using various optical techniques that also have advantageous surface chemical properties as explicitly taught by van Damme et al (column 2, lines 1-20). In addition, it would have been obvious to the ordinary artisan that the known technique of using the transparent metal oxide flow-through support member having the channel orientation as taught by van Damme et al could have been used as the aluminum oxide flow-through support member in the device of the '397 claims in view of Ligler et al with predictable results because the known technique of using the transparent metal oxide flow-through support member

having the channel orientation as taught by van Damme et al predictably results in use of a reliable flow-through support member.

This is a provisional obviousness-type double patenting rejection.

19. Claim 9 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 47-49 and 51-53 of copending Application No. 11/662,397 in view of Ligler et al (U.S. Patent Application Publication No US 2002/0028475 A1, published 7 March 2002) as evidenced by the online dictionary at merriam-webster.com [retrieved on 2009-08-05; Retrieved from the Internet: <URL: www.merriam -webster.com/dictionary/tube>] and further as evidenced by Stanchfield et al (U.S. Patent No. 6,436,350 B1, issued 20 August 2002) as applied to claim 1 above, and further in view of Fields (U.S. Patent Application Publication No. US 2003/0027203 A1, published 9 February 2003)

Regarding claim 9, the device of claim 1 is discussed above in Section 17.

Neither the '397 claims nor Ligler et al do not explicitly teach the device of claim 1 is part of the apparatus comprising the additional limitations of claim 9.

However, Fields teaches an apparatus having a handling station comprising a handling device; namely, an automated apparatus comprising a handling station comprising a handling device in the form of a robotic pipettor that transports pipette tips (paragraph 0065). The pipettor aspirates and dispenses fluids in the tip (paragraph 0065), and is thus a handling station comprising a handling device in accordance with the embodiment described on page 14 of the instant specification. The apparatus

further comprises a robotic translation system for moving the handling station (i.e., pipette tips) in the form of a robotic arm (Figure 7 and paragraph 0065), which is a "means for transporting" in accordance with the embodiment of a means for transporting described on page 18 of the instant specification. The apparatus of Fields also comprises an incubation section in the form of a region of the device that comprises a heating block, which is a, incubation device for incubating the sample because the specification contains no limiting definition of an incubation section comprising an incubation device. Fields further teaches the apparatus comprises an analysis section comprising a detection assembly in the form of a fluorescence detector (claim 20 of), which is in accordance with the embodiment of a "detection means" presented on pages 16-17 of the instant specification. Thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "handling station" a "handling device" a "means for transporting," and "incubation section comprising an incubation device," and "an analysis section comprising a detection device."

Fields also teaches the use of a tip wherein nucleic acids bind to a porous material within a tip (Figures 8-9 and paragraphs 0067-0068). The tip is a tubular housing having a proximal end and a distal end defining an internal flow passageway (Figures 8-9). The housing comprises flow-through support material 73 provided therein to obstruct the internal passageway. The support member is a porous material capable of binding nucleic acids (paragraph 0067). Fields also teaches the apparatus has the

added advantage of allowing automatic detection of target sequences from fresh blood samples (Abstract).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the device of the '397 claims in view of Ligler et al so that the device is part of the apparatus taught Fields to arrive at the instantly claimed inventions with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a device having the added advantage of allowing automatic detection of target sequences from fresh blood samples as explicitly taught by Fields (Abstract).

This is a provisional obviousness-type double patenting rejection.

20. Claims 1-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 47-49 and 51-53 of copending Application No. 11/662,397 in view of Raybuck et al (U.S. Patent No. 5,556,598, issued 17 September 1996).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 47-49 and 51-53 of the '397 Application describe all of the limitations of the claims in the instant application; e.g., device comprising a flow-through support member (i.e., a solid porous support) comprising a metal (i.e., conductive material) and having channels therethorugh, and aluminum oxide. For example, instant claim 4 is drawn to a device having a flow-through support member

(i.e., a solid porous support) comprising a metal (i.e., conductive material) and having channels therethorugh, wherein the support member is aluminum oxide. These limitations are met by claims 51 and 47-49 of the '397 claims. The additional limitations of the '397 claims are encompassed by the open claim language "comprising" found in the instant claims.

The '397 claims do not require the support member of the device be in a tubular housing.

However, Raybuck et al teach a device comprising a tubular housing have a proximal end and a distal end defining an internal flow passageway; namely, Figure 6 shows a tubular housing in the form of pipette tip 10, which is shown having a proximal and distal end (i.e., the ends of the tip; column 8, line 58-column 9, line 55). The housing is further provided with a flow-through support member in the form of substrate 17 (column 7, lines 15-30), which obstructs the internal passage way of the housing (Figure 6). Substrate 17 is a membrane that is porous (column 5, lines 30-50), and thus comprises through going channels in accordance with the embodiment described in lines 24-35 on page 6 of the instant specification.

Raybuck et al also teach the support member is provided with capture entities immobilized on the membrane (i.e., claim 2; column 5, lines 50-60); the support member is provided at or near the distal end of the housing (i.e., claim 3; Figure 6); the support member is optically transparent (i.e., claim 5; column 6, lines 10-20); the plane of the support member extends substantially perpendicular with the longitudinal axis of the housing (i.e., claim 7; Figure 6); and the support member is placed entirely across the

opening end of tubular housing (i.e., claim 8; Figures 2D-E). Raybuck et al also teach the device has the added advantage of allowing use on a micro-pipette (Abstract).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the apparatus of the '397 claims to comprise the tubular housing of Raybuck et al to arrive at the instantly claimed apparatus with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in an apparatus having the added advantage of allowing use on a micro-pipette as explicitly taught by Raybuck et al (Abstract).

This is a provisional obviousness-type double patenting rejection.

21. Claims 4-6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 47-49 and 51-53 of copending Application No. 11/662,397 in view of Raybuck et al (U.S. Patent No. 5,556,598, issued 17 September 1996) as applied to claim 1 above, and further in view of van Damme et al (U.S. Patent No. 6,225,131 B1, issued 1 May 2001).

It is noted that while claims 4-5 have been rejected as described above in Section 20, the claims are also obvious using the alternative interpretation outlined below.

Regarding claims 4-6, the device of claim 1 is discussed above in Section 20.

Neither the '397 claims nor Raybuck et al explicitly teach the channels of the aluminum oxide membrane are substantially coaxial with the longitudinal axis of the housing (i.e., claim 6).

However, van Damme et al teach flow-through support members in the form of transparent aluminum oxide membranes (i.e., claims 4-5) that are transparent (column 2, lines 5-15). The channels of the membrane are through going oriented channels that allow flow-through the membranes (column 3, lines 25-45), and are oriented perpendicular to the surface of sample application (claim 1 of van Damme). Van Damme et al also teach the membranes have the added advantage of allowing for assays using various optical techniques that also have advantageous surface chemical properties (column 2, lines 1-20). Thus, van Damme et al teach the known technique of using a flow-through support member that is a metal oxide (i.e., claim 4), transparent (i.e., claim 5), and has channels perpendicular to the flow direction (i.e., claim 6).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the device of the '397 claims in view of Raybuck et al so that the aluminum oxide membrane is the transparent aluminum oxide flow-through membrane (i.e., claims 4-5) having the channels perpendicularly oriented to the direction of flow as taught van Damme et al. Orientation of the membrane to allow flow-through that is perpendicular to the channels results in placement of the membrane so that the channels extend substantially coaxial with the longitudinal axis of the housing (i.e., claim 6), thus arriving at the instantly claimed device with a reasonable expectation of success. The ordinary artisan would have

been motivated to make the modification because said modification would have resulted in a device having the added advantage of allowing for assays using various optical techniques that also have advantageous surface chemical properties as explicitly taught by van Damme et al (column 2, lines 1-20). In addition, it would have been obvious to the ordinary artisan that the known technique of using the transparent metal oxide flow-through support member having the channel orientation as taught by van Damme et al could have been used as the aluminum oxide flow-through support member in the device of the '397 claims in view of Raybuck et al with predictable results because the known technique of using the transparent metal oxide flow-through support member having the channel orientation as taught by van Damme et al predictably results in use of a reliable flow-through support member.

This is a provisional obviousness-type double patenting rejection.

22. Claim 9 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 47-49 and 51-53 of copending Application No. 11/662,397 in view of Raybuck et al (U.S. Patent No. 5,556,598, issued 17 September 1996) as applied to claim 1 above, and further in view of Fields (U.S. Patent Application Publication No. US 2003/0027203 A1, published 9 February 2003)

Regarding claim 9, the device of claim 1 is discussed above in Section 20.

Neither the '397 claims nor Raybuck et al explicitly teach the device comprises the additional limitations of the apparatus of claim 9.

However, Fields teaches an apparatus having a handling station comprising a handling device; namely, an automated apparatus comprising a handling station comprising a handling device in the form of a robotic pipettor that transports pipette tips (paragraph 0065). The pipettor aspirates and dispenses fluids in the tip (paragraph 0065), and is thus a handling station comprising a handling device in accordance with the embodiment described on page 14 of the instant specification. The apparatus further comprises a robotic translation system for moving the handling station (i.e., pipette tips) in the form of a robotic arm (Figure 7 and paragraph 0065), which is a "means for transporting" in accordance with the embodiment of a means for transporting described on page 18 of the instant specification. The apparatus of Fields also comprises an incubation section in the form of a region of the device that comprises a heating block, which is a, incubation device for incubating the sample because the specification contains no limiting definition of an incubation section comprising an incubation device. Fields further teaches the apparatus comprises an analysis section comprising a detection assembly in the form of a fluorescence detector (claim 20 of), which is in accordance with the embodiment of a "detection means" presented on pages 16-17 of the instant specification. Thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "handling station" a "handling device" a "means for transporting," and "incubation section comprising an incubation device," and "an analysis section comprising a detection device."

Fields also teaches the use of a tip wherein nucleic acids bind to a porous material within a tip (Figures 8-9 and paragraphs 0067-0068). The tip is a tubular housing having a proximal end and a distal end defining an internal flow passageway (Figures 8-9). The housing comprises flow-through support material 73 provided therein to obstruct the internal passageway. The support member is a porous material capable of binding nucleic acids (paragraph 0067). Fields also teaches the apparatus has the added advantage of allowing automatic detection of target sequences from fresh blood samples (Abstract).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the device of the '397 claims in view of Raybuck et al so that the device is part of the apparatus taught Fields to arrive at the instantly claimed inventions with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a device having the added advantage of allowing automatic detection of target sequences from fresh blood samples as explicitly taught by Fields (Abstract).

This is a provisional obviousness-type double patenting rejection.

23. Claim 11 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 47-49 and 51-53 of copending Application No. 11/662,397 in view of Raybuck et al (U.S. Patent No. 5,556,598, issued 17 September 1996) as applied to claim 1 above, and further in view of Ligler et al (U.S. Patent Application Publication No US 2002/0028475 A1, published 7 March 2002)

Regarding claim 11, the device of claim 1 is discussed above in Section 20.

Neither the '397 claims nor Raybuck et al teach the pore sizes of the instant claims.

However, Ligler et al teach a device comprising a housing in the form of column 14, which has a proximal end in to form of an open tip and a distal end in the form of the open top end of Figure 1 (paragraph 0032) and which further comprises a flow-through support member in the form of porous membrane 12 (Figure 1 and paragraph 0032); the housing therefore defines an internal flow passageway. Porous membrane 12 is made of a metal oxide; namely, aluminum oxide (paragraph 0023), and obstructs the internal passageway of the housing (Figure 1). The membrane comprises through going channels (i.e., pores) suitable for allowing an interaction between target and probe molecules; namely, binding elements are immobilized throughout the thickness of the membrane (i.e., in the channels; paragraph 0024), wherein the binding elements are antibodies and are thus probes suitable for binding to a target analyte (paragraph 0025). The through going channels have a pore size diameter between 50 and 400 nm; namely, the pore sizes are about 0.2 microns (paragraph 0022), which is about 200 nm. The channels also comprise probes; namely, binding elements are immobilized throughout the thickness of the membrane (i.e., in the channels; paragraph 0024), wherein the binding elements are antibodies and are thus probes suitable for binding to a target analyte (paragraph 0025). Ligler et al also teach the aluminum oxide membrane has the added advantage of providing a fast flow-through rate and allowing reuse (paragraph 0021).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the apparatus comprising a tubular housing having a porous flow-through support material of the '397 claims in view of Raybuck et al so that the support material is the aluminum oxide membrane having the pore sizes of Ligler et al to arrive at the instantly claimed device with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in an apparatus having the added advantage of having an aluminum oxide membrane that provides a fast flow-through rate and allows reuse as explicitly taught by Ligler et al (paragraph 0021).

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

24. Applicant's arguments filed 19 May 2009 (hereafter the "Remarks") have been fully considered but they are not persuasive for the reason(s) discussed below.

A. Applicant's arguments with respect to the previous rejections of the claims over Stimpson et al (i.e., US 6,306,664) and Fields (i.e., US 2003/0027203) have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendments.

B. Applicant argues on pages 8-9 of the Remarks that Raybuck et al (i.e., US 5,556,598) teach that the membranes are preferably a woven on non-woven mesh, and thus does not teach through-going channels. Applicant does not provide any citation of Raybuck et al in support of this argument.

However, it is noted that a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories,* 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Upsher-Smith Labs. v. Pamlab, LLC*, 412 F.3d 1319, 1323, 75 USPQ2d 1213, 1215 (Fed. Cir. 2005)(reference disclosing optional inclusion of a particular component teaches compositions that both do and do not contain that component); Celeritas Technologies Ltd. v. Rockwell International Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed."). Thus, the statement in column 5, lines 35-55) of Raybuck et al that the membrane is preferably woven encompasses the alternate embodiment wherein the membrane is **not** woven. See MPEP § 2123 [R-5].

In addition, as noted in the rejections above, substrate 17 is a membrane that is porous (column 5, lines 30-50), and thus comprises through going channels in accordance with the embodiment described in lines 24-35 on page 6 of the instant specification. Thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "channel."

C. Applicant argues on page 9 of the Remarks that Raybuck et al teaches the membrane is made of organic polymers, and thus does not teach a silicon oxide.

However, as discussed above and as admitted by Applicant on page 9 of the Remarks, Raybuck et al teach glass membranes (column 6, lines 1-10).

Thus, as noted in the rejections above, the recitation of membrane that is "a silicon oxide" is deemed to be inherent in the glass membrane of Raybuck et al, as evidenced by Beattie, which teaches that glass is SiO2, which is an oxide of silicon (column 2, lines 20-25). The burden is on Applicant to show that the claimed membrane that is "a silicon oxide" is either different or non-obvious over the glass membrane of Raybuck et al.

Alternatively, Beattie teaches the attachment of biomolecules (i.e., probes) to glass, wherein the glass is an oxide of silicon (column 2, lines 10-30), which has the added advantage of allowing improved stable attachment of the probes to the surface without requiring derivatization (Abstract). Thus, Beattie teaches the known technique of using glass that is an oxide of silicon, and the claims are obvious for the reasons presented above.

Conclusion

25. No claim is allowed.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571)272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert T. Crow
Examiner
Art Unit 1634

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